WOMEN'S & MEN'S HEALTH—Quality of Life Studies

PWH3

PULSED OESTROGEN THERAPY WITH INTRANASAL 17-B OESTRADIOL IMPROVES WOMEN'S QUALITY OF LIFE IN THE EARLY POSTMENOPAUSAL PERIOD

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OBJECTIVES: To assess influence of HRT with the pulsed oestrogen therapy, on the women's quality of life in the early postmenopausal period. **METHODS:** Quality of life (QoL) data were derived from the prospective, clinical, open study carried out in the 16 centres in Poland. The sample consisted of 102 females at the mean age of 52, reporting climacteric symptoms. QoL was assessed at the baseline (V-0), after 12 weeks (V-12) and after 16 weeks (V-16) of active treatment. Two instruments were used: generic Short Form Health Survey (SF-36) and median-aged women specific—Women's Health Questionnaire (WHQ). The scoring was processed according to the questionnaire's manuals. Statistical significance of the results obtained in comparison with baseline were compared using the Wilcoxon signed—rank test. **RESULTS:** Mean value of SF-36 Mental Component Summary (MCS) was 35.2 ± 10.7 at V-0 and 50.4 ± 8.1 at V-16. Mean value of SF-36 Physical Summary Measure (PCS) was 46.4 ± 7.8 at V-0 and 52.4 ± 5.5 at V-16. Mean values for the particular dimensions of the WHQ for V-0 and respectively for V-16 were as follows: depressed mood; 0.50 ± 0.26 and 0.89 ± 0.16, somatic symptoms; 0.39 ± 0.25 and 0.84 ± 0.21, memory and concentration; 0.35 ± 0.36 and 0.80 ± 0.28, vasomotor symptoms; 0.08 ± 0.23 and 0.96 ± 0.17, anxiety and fears; 0.46 ± 0.28 and 0.90 ± 0.2, sexual behaviour; 0.48 ± 0.38 and 0.69 ± 0.34, sleep problems; 0.25 ± 0.31 and 0.87 ± 0.25, menstrual symptoms; 0.68 ± 0.29 and 0.93 ± 0.15, attractiveness; 0.46 ± 0.53 and 0.62 ± 0.38. Differences observed in QoL are statistically significant with the $p < 0.05$. **CONCLUSIONS:** Pulsed oestrogen therapy achieved by intranasal oestradiol 300 µg has a positive impact on womens' general QoL and symptoms related QoL measured in early postmenopausal period. Improvement is expressed in all of the eight SF-36 scales and in all of the WHQ dimensions.

PWH4

VASOMOTOR SYMPTOMS AND QUALITY OF LIFE (QOL) IN POSTMENOPAUSAL WOMEN

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OBJECTIVES: To measure the impact of vasomotor symptoms on QoL based on a sample of 1655 healthy, nonhysterectomized, postmenopausal women aged 40 to 65 who were not on hormonal treatment. **METHODS:** QoL was assessed with the Women's Health Questionnaire (WHQ) and the SF-36. Subgroup analyses were conducted for women with 1) at least 7 moderate to severe hot flushes per day as reported on daily diary cards over a 1-week period; 2) at least one but less than 7 moderate to severe hot flushes per day over the same period; and 3) no hot flushes. **RESULTS:** Seven percent (7%) of study participants were in subgroup 1.64% in subgroup 2, and 29% in subgroup 3. Women in subgroup 1 had significantly worse scores ($p < 0.05$) than women in subgroup 3 on 8 of 9 WHQ domains (all but attractiveness) and 4 of 8 SF-36 subscales (vitality, bodily pain, social function, and role limitations-emotional) and the mental composite score. Women in subgroup 1 had significantly worse scores ($p < 0.05$) than women in subgroup 2 on 5 WHQ domains (vasomotor symptoms, sleep problems, sexual behavior, somatic symptoms and depressed mood) and 2 SF-36 subscales (vitality and social function). Women in subgroup 2 had significantly worse scores ($p < 0.05$) than women in subgroup 3 on 5 WHQ domains (vasomotor symptoms, sleep problems, somatic symptoms, memory/concentration, and menstrual symptoms) and 2 SF-36 subscales (vitality and role limitations-emotional) and the mental composite score. For each intergroup comparison, absolute score differences for the SF-36 were smaller than those for the WHQ, but always exceeded at least 4 points out of 100 for statistically significant differences. **CONCLUSIONS:** Women with moderate to severe hot flushes experience a significant decrease in quality of life as measured by the WHQ and SF-36. Wyeth Research supported this project.

PWH5

QUALITY OF LIFE (QOL) DIFFERENTIATION ANALYSIS IN PATIENTS UNDERGOING CONTROLLED OVARIAN STIMULATION (COS) WITH TWO DIFFERENT PREPARATIONS OF RECOMBINANT HUMAN FOLLICLE-STIMULATING HORMONE (R-HFSH)

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OBJECTIVES: Differences in drug effects on the QOL of patients undergoing assisted reproductive techniques have been little. The objective of this study was to perform a QOL analysis using the Short Form-36 combined with mathematical modeling to determine whether differences in QOL exist between patients undergoing COS with follitropin alfa (Gonal-FÒ, Serono) and follitropin beta (FollistimÒ/PuregonÒ liquid, Organon). **METHODS:** The

SF-36 questionnaire was administered to patients who received COS with follitropin alfa (n = 22) or follitropin beta (n = 21) in a randomized controlled clinical study. SF-36 scores before and after COS were obtained for each patient. Results for the eight "dimensions" of the SF-36 were projected using multifactorial analysis to produce a composite QOL score. Statistical tests were performed to determine the percentage of relevant information captured by the multifactorial analysis and hence the quality of the composite score. The bootstrap technique was used to generate additional random samples. The Kolmogorov–Smirnov test was used to compare the distributions of the composite scores for the follitropin alfa and beta groups. **RESULTS:** The test performed to validate the composite QOL score gave a value of 0.55 (55% of relevant information captured), compared with an expected score of 0.125 for a random projection of eight dimensions into one. The distribution of composite scores for the two groups was significantly different after 30 simulations ($p = 0.004$), suggesting a difference in the effects of the two treatments on QOL. A graphical plot of the results of 5000 simulations showed that the follitropin beta group had a greater reduction in QOL as a result of COS compared with the follitropin alfa group. **CONCLUSIONS:** Mathematical modeling confirms a statistically significant difference in QOL effects of the two r-hFSH preparations in favor of follitropin alfa.

PWH6

PATIENT AND PARTNER TREATMENT SATISFACTION SCALE (TSS) IN ERECTILE DYSFUNCTION

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OBJECTIVE: To develop an instrument to assess male patient's and their female partner's satisfaction with the treatment for erectile dysfunction (ED) and assess the comprehensiveness, comprehension, acceptability and clarity of the instrument. **METHODS:** Four phases were performed in the questionnaire development; item generation, face and content validity, cognitive debriefing, cultural and language adaptation. Item generation was based on literature review, hypothesized characteristics of the drug and in-depth interviews with patients and their partners. Perceptions and feelings related to the condition and their expectations of treatment were examined. Items were generated simultaneously in English, French, and German and adapted to each culture. Content and face validity were assessed by interviews with patients and partners in 5 countries. Testing of structure and response scales, cognitive debriefing and verification of conceptual equivalence between languages was assessed. **RESULTS:** A total of 55 interviews were conducted to test face and content validity for patients, partners and experts. The final content areas deemed important included spontaneity, quality of erection, quality of ejaculation, sexual pleasure, satisfaction with orgasm, confidence, reliability of treatment, side effect, convenience, overall satisfaction, conformity to treatment expectations and intentions for continued use of drug. Cognitive debriefing with patients and partners found no problems with comprehension. Results of the debriefing found some words to be problematic. There were no cultural differences found between the English, French, or German version. The questionnaire was revised at each phase. The final questionnaire for both the patient and the partner contained 19 questions. The questionnaire was then translated into 14 additional languages for use in clinical trials. **CONCLUSIONS:** The TSS is a comprehensive measure of male ED patients and their respective partners. Further work is needed to validate the TSS, identify the domains, test the responsiveness and determine the appropriate scoring.

PWH7

A NEW INSTRUMENT TO MEASURE THE PSYCHOLOGICAL IMPACT OF ERECTILE DYSFUNCTION. VALIDATION OF A SPANISH VERSION OF THE JOHNSON AND MCCOY'S SELF-CONFIDENCE SCALE

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Erectile dysfunction has an impact on Health Related Quality of Life. It can be expected that it also has some impact on psychological well-being-related variables, such as self-confidence and self-esteem. It is, therefore, worthwhile making available in different languages validated versions of instruments able to measure these parameters. **OBJECTIVE:** To perform the linguistic and psychometric validation of a cultural adaptation to Spanish of the Johnson and McCoy's Self-Confidence Scale to be used in patients with erectile dysfunction (ED). **METHODS:** After conducting a linguistic validation of the scale through two forward translations, backward translation, and cognitive debriefing interviews the final reconciled version of the scale was to be administered to 200 male patients with ED and 200 male subjects without ED. Participants were screened for ED by general practitioners and further reviewed by urologists. In addition to the self-confidence scale, all participants were asked to answer the Rosenberg's self-esteem scale. **RESULTS:** A total of 387 subjects completed the self-confidence questionnaire. It showed a high internal consistency (Cronbach's alpha = 0.82), similar to the original English version (Cronbach's alpha = 0.84). All items showed a high correlation with the scale. The correlation of the scale with self-esteem score was adequate ($r = 0.60$). A factorial structure of 5 dimensions was observed in the Spanish version of the self-confidence scale comparable to the original structure. Self-confidence scores were